

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X	:	
BAYER HEALTHCARE LLC,	:	
	:	
Plaintiff,	:	
	:	1:11-cv-3047-AKH
v.	:	
	:	<u>ANSWER AND JURY DEMAND</u>
ELI LILLY AND COMPANY,	:	
	:	
Defendant.	:	
-----X	:	

Defendant Eli Lilly and Company (“Lilly”), by and through its undersigned counsel, files its Answer and Affirmative Defenses to Plaintiff Bayer Healthcare LLC’s (hereinafter “Bayer Animal Health” or “BAH”) Complaint and shows the Court as follows:

1. Lilly admits that Elanco Animal Health (“Elanco”) is a division of Eli Lilly and Company and that Elanco and Bayer Animal Health both sell pet medicines. Lilly denies allegations that Elanco is, or has been, engaged in an unfair or deceptive campaign to convince distribution agents and veterinarians to terminate business relations with BAH. The remaining allegations in Paragraph 1 of the Complaint state legal conclusions to which no responsive pleading is required. To the extent a response is required, Lilly denies the remaining allegations contained in Paragraph 1 of the Complaint.

2. Lilly admits that Elanco sells its products exclusively to veterinarians, including pet hospitals and veterinary clinics, and that these sales may be made either directly to the veterinarian, hospital, or clinic or through a distributor or distribution agent. Lilly admits that BAH sells pet medicines through retail stores. Lilly admits that diversion of product occurs which is why Elanco has implemented a “Track and Trace” program designed support the

veterinary channel. Lilly denies the remaining allegations contained in Paragraph 2 of the Complaint.

3. Lilly denies the allegations contained in Paragraph 3 of the Complaint.

4. Upon information and belief, Lilly admits that Bayer Healthcare LLC is a limited liability company organized and existing under the laws of the state of Delaware. Lilly is without knowledge or information regarding the complete details of the distribution of Bayer products. Upon information and belief, Lilly admits that Bayer products are sold in various locations in the United States. Lilly denies the remaining allegations in Paragraph 4 of the Complaint.

5. Lilly admits that it is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly further admits that Elanco is a division of Lilly with its principal place of business located in Greenfield, Indiana and that Elanco manufactures the FDA- and EPA-approved companion animal products Comfortis<sup>®</sup> (spinosad), Assurity<sup>™</sup>, and Trifexis<sup>™</sup> (spinosad + milbemycin oxime). In further response, Lilly admits it sells its products throughout the United States. Lilly denies the remaining allegations in Paragraph 5 of the Complaint.

6. The allegations contained in the first sentence of Paragraph 6 of the Complaint state legal conclusions to which no responsive pleading is required. In further response, Lilly denies jurisdiction is proper under 28 U.S.C. § 1332. To the extent a response is required, Lilly denies the remaining allegations contained in Paragraph 6 of the Complaint.

7. Lilly admits that Elanco pet medicines are sold in the State of New York. The remaining allegations contained in Paragraph 7 of the Complaint state legal conclusions to which no responsive pleading is required. To the extent a response is required, Lilly denies the remaining allegations contained in Paragraph 7 of the Complaint.

8. The allegations contained in Paragraph 8 of the Complaint state legal conclusions to which no responsive pleading is required. To the extent a response is required, Lilly denies any remaining allegations contained in Paragraph 8 of the Complaint.

9. Lilly admits that Elanco and Bayer Animal Health both sell pet medicines and that Lilly manufactures flea preventatives for cats and dogs. Lilly denies the remaining allegations set forth in Paragraph 9 of the Complaint.

10. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 10 of the Complaint, and therefore, such allegations are denied at this time.

11. Lilly admits that Elanco has been manufacturing animal health products for nearly 60 years and that in 2007 Elanco launched Comfortis<sup>®</sup>, an FDA-approved, chewable, beef-flavored tablet that kills fleas and prevents flea infestations on dogs for a full month. Elanco also manufactures: Reconcile<sup>®</sup>, an FDA-approved beef-flavored tablet for dogs that treats separation anxiety in conjunction with a behavior modification plan; Assurity<sup>™</sup>, a new EPA-approved flea product for cats; and Trifexis<sup>™</sup>, an FDA-approved monthly chewable tablet for dogs that kills fleas, prevents heartworm disease and treats and controls adult hookworm, roundworm and whipworm infections. Lilly denies the remaining allegations set forth in Paragraph 11 of the Complaint.

12. Lilly admits that Novartis, Merial, Pfizer, Merck, Hartz, and Farnam sell pet medicines. Lilly specifically denies that it has used unfair and illegal tactics. The remaining allegations of Paragraph 12 of the Complaint state legal conclusions to which no responsive pleading is required. To the extent a response is required, Lilly denies the remaining allegations contained in Paragraph 12 of the Complaint.

13. Lilly admits that Elanco sells its products exclusively to veterinarians, including pet hospitals and veterinary clinics, and that these sales may be made either directly to the veterinarian, hospital, or clinic or through a distributor or distribution agent. Elanco also admits that other manufacturers, including BAH, sell their products directly to retailers. Lilly is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 13 of the Complaint, and therefore, such allegations are denied at this time.

14. Lilly admits that its Comfortis<sup>®</sup>, Reconcile<sup>®</sup>, and Trifexis<sup>™</sup> products are FDA-approved and regulated. Lilly further admits that these products are available only with a prescription from a licensed veterinarian. These products are not legally available over-the-counter through retail (i.e., non-pharmacy) channels. Lilly is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 14 of the Complaint, and therefore, such allegations are denied at this time.

15. Lilly admits that BAH sells its Advantage and K9 Advantix product lines over-the-counter through retail channels. Lilly further admits that Assurity<sup>™</sup> is an EPA-approved product that does not require a prescription from a licensed veterinarian, although Elanco distributes Assurity<sup>™</sup> exclusively through veterinarians. Lilly is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 15 of the Complaint, and therefore, such allegations are denied at this time.

16. Lilly admits that Elanco sold and continues to sell its pet medicines exclusively to veterinarians, including pet hospitals and veterinary clinics, and that these sales may be made either directly to the veterinarian, hospital, or clinic or through a distributor or distribution agent. Lilly is without knowledge or information sufficient to form a belief as to the truth of whether

BAH sold its entire line of pet medicines exclusively to veterinarians until March of 2010. Lilly denies the remaining allegations set forth in Paragraph 16 of the Complaint.

17. Lilly admits that Elanco did not and does not sell its pet medicines to retail stores or internet pharmacies. Lilly admits that diversion of Elanco's products violates the terms of Elanco's sales policy. Lilly admits that veterinary diversion occurred and that Bayer and Merial products were available through retail channels and on the internet. Lilly is without knowledge or information sufficient to form a belief as to the truth of the remaining additional allegations regarding BAH and Merial contained in Paragraph 17 of the Complaint, and therefore, such allegations are denied at this time.

18. Lilly admits that BAH announced its decision to sell its products through the retail channel. Lilly is without knowledge or information sufficient to form a belief as to the truth of the additional allegations contained in the first and second sentences of Paragraph 18 of the Complaint, and therefore, such allegations are denied at this time. Lilly denies the remaining allegations contained in Paragraph 18 of the Complaint.

19. Lilly admits that veterinarians and veterinary clinics still stock some amount of BAH products. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 19 of the Complaint, and therefore, such allegations are denied at this time.

20. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 20 of the Complaint, and therefore, such allegations are denied at this time. By way of further response, the study referenced in Paragraph 20 and its underlying data speaks for themselves, and any characterization of that study by BAH is denied.

21. Lilly admits that in April of 2010, Elanco sent a Dear Doctor Letter (“the Letter”) to a number of veterinarians in the United States. The Letter referenced in Paragraph 21 speaks for itself, and any characterization of the Letter by BAH is denied. Lilly denies the remaining allegations contained in Paragraph 21 of the Complaint.

22. The excerpt from the Letter referenced in Paragraph 22 speaks for itself, and any characterization of the Letter by BAH is denied.

23. Lilly denies the allegations contained in Paragraph 23 of the Complaint.

24. Lilly admits that the study referenced in Paragraph 24 did not assess the availability of pet medicines in retail stores as a factor in the decline of veterinary usage or as a factor in the decline in veterinarian-dispensed flea medications. By way of further response, the study, and its underlying data, speak for themselves and any characterization of the study by BAH is denied. Lilly denies the remaining allegations contained in Paragraph 24 of the Complaint.

25. Lilly denies the allegations contained in Paragraph 25 of the Complaint.

26. The Letter referenced in Paragraph 26 speaks for itself, and any characterization of the Letter by BAH is denied. Lilly is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 26 of the Complaint, and therefore, such allegations are denied at this time.

27. The Letter referenced in Paragraph 27 speaks for itself, and any characterization of the Letter by BAH is denied. To the extent there are additional factual allegations contained in Paragraph 27, Lilly denies those allegations. Insofar as any remaining allegations state legal conclusions, no responsive pleading is required.

28. The Letter referenced in Paragraph 28 speaks for itself, and any characterization of the Letter by BAH is denied. Lilly denies the remaining allegations contained in Paragraph 28 of the Complaint.

29. Lilly admits that diversion of product occurs which is why Elanco has implemented a “Track and Trace” program designed to support the veterinary channel. Lilly denies the remaining allegations contained in Paragraph 29 of the Complaint.

30. Lilly denies the allegations contained in Paragraph 30 of the Complaint.

31. The Letter referenced in Paragraph 31 speaks for itself, and any characterization of the Letter by BAH is denied. Lilly denies the remaining allegations contained in Paragraph 31 of the Complaint.

32. Lilly admits that Elanco received a letter from Bayer dated April 29, 2011. That letter speaks for itself. Lilly denies the remaining allegations contained in Paragraph 32 of the Complaint.

33. Lilly admits that Elanco has hired individuals who may be former Bayer employees. Lilly denies the remaining allegations contained in Paragraph 33 of the Complaint.

34. Lilly admits that in April of 2011, Elanco sent out the Letter. To the extent the allegations in Paragraph 34 reference the Letter, the Letter speaks for itself. Lilly further admits that Elanco promotes its products to veterinarians and distribution agents. Lilly denies the remaining allegations contained in Paragraph 34 of the Complaint.

35. Lilly denies the allegations contained in Paragraph 35 of the Complaint.

**COUNT I: FALSE ADVERTISING  
UNDER SECTION 43(a) OF THE LANHAM ACT**

36. In response to the allegations contained in Paragraph 36 of the Complaint, Lilly adopts and incorporates the responses to Paragraph 1 through 35 of the Complaint as though set forth in full herein.

37. Lilly denies the allegations contained in Paragraph 37 of the Complaint.

38. Lilly denies the allegations contained in Paragraph 38 of the Complaint.

39. Lilly denies the allegations contained in Paragraph 39 of the Complaint.

40. Lilly denies the allegations contained in Paragraph 40 of the Complaint.

41. Lilly denies the allegations contained in Paragraph 41 of the Complaint.

**COUNT II: FALSE ADVERTISING  
UNDER STATE LAW**

42. In response to the allegations contained in Paragraph 42 of the Complaint, Lilly adopts and incorporates the responses to Paragraph 1 through 41 of the Complaint as though set forth in full herein.

43. Lilly denies the allegations contained in Paragraph 43 of the Complaint.

44. Lilly denies the allegations contained in Paragraph 44 of the Complaint.

45. Lilly denies the allegations contained in Paragraph 45 of the Complaint.

**COUNT III: UNFAIR COMPETITION  
UNDER STATE COMMON LAW**

46. In response to the allegations contained in Paragraph 46 of the Complaint, Lilly adopts and incorporates the responses to Paragraph 1 through 45 of the Complaint as though set forth in full herein.

47. Lilly denies the allegations contained in Paragraph 47 of the Complaint.

**PRAYER FOR RELIEF**



Lilly denies that Bayer Animal Health is entitled to any form of relief sought in its Prayer for Relief, including Paragraphs A(i)(ii)(iii), B, C, D, E, F, G H, and I or to any other form of relief whatsoever.

Any allegation heretofore neither admitted nor denied is now hereby expressly denied.

### **AFFIRMATIVE DEFENSES**

Without assuming any burdens not imposed by law, Lilly asserts the following defenses to BAH's claims:

#### **FIRST DEFENSE**

BAH's Complaint fails to state a claim for which relief can be granted.

#### **SECOND DEFENSE**

This Court lacks subject matter jurisdiction over one or more of BAH's claims.

#### **THIRD DEFENSE**

The claims contained in BAH's Complaint should be dismissed due to improper venue.

#### **FOURTH DEFENSE**

BAH's claims may be barred by the applicable statute of limitations.

#### **FIFTH DEFENSE**

This Court should decline to exercise jurisdiction under the doctrine of forum non conveniens. Venue is proper in the United States District Court for the Southern District of Indiana, and this case should be transferred to that venue pursuant to 28 U.S.C. § 1404.

#### **SIXTH DEFENSE**

The claims contained in BAH's Complaint are barred by the doctrine of unclean hands.

**SEVENTH DEFENSE**

The claims asserted in BAH's Complaint are barred for failure to plead with the requisite particularity under Fed R. Civ. P. 8.

**EIGHTH DEFENSE**

The claims contained in BAH's Complaint are barred by the doctrine of laches, waiver, and estoppel.

**NINTH DEFENSE**

BAH's requested monetary relief is too speculative, remote, and/or impossible to prove and/or allocate.

**TENTH DEFENSE**

BAH's claims for equitable relief are barred to the extent there is an adequate remedy at law.

**ELEVENTH DEFENSE**

BAH's claims are barred because it lacks standing to assert some or all of its causes of action.

**TWELFTH DEFENSE**

Any damages BAH has sustained, and the same is expressly denied, were not caused by an act or omission on the part of Lilly.

**THIRTEENTH DEFENSE**

BAH's claims are barred to extent any complained of statements by Lilly did not cause injury and/or are not likely to cause injury.

**FOURTEENTH DEFENSE**

BAH's claims are barred to extent any complained of statements by Lilly are not likely to influence purchasing decisions.

**FIFTEENTH DEFENSE**

Any damages BAH has sustained, and the same is expressly denied, have been proximately caused or occasioned by acts of third parties, other competitors, other sources of information, BAH's own conduct, advertising and marketing, or other actions not attributable to Lilly. Lilly therefore pleads independent, intervening and/or superseding acts or omission of BAH or others as a complete bar to this action.

**SIXTEENTH DEFENSE**

BAH's claims are barred because the Lilly's statements are protected by the First Amendment to the United States Constitution, and other applicable, equivalent state laws and doctrine protecting freedom of speech from unreasonable or unjustified restriction.

**SEVENTEENTH DEFENSE**

BAH's claims are barred to the extent complained of statements were directed at sophisticated consumers and/or purchasers.

**EIGHTEENTH DEFENSE**

BAH's claims are barred to extent any complained of statements by Lilly did not actually deceive or tend to deceive.

**NINETEENTH DEFENSE**

BAH's claims are barred to extent any complained of statements by Lilly which constitute an alleged misrepresentation are not false or misleading.

**TWENTIETH DEFENSE**

BAH's claims are barred to extent any complained of statements by Lilly did not occur in commercial advertising or promotion.

**TWENTY-FIRST DEFENSE**

BAH's claims are barred to extent any complained of statements did not concern the nature, characteristics, qualities, or geographic origin of BAH's goods, services, or commercial activities.

**TWENTY-SECOND DEFENSE**

Any inaccuracies in the Letter or any of Lilly's advertising or published information concerning its products or the BAH, and the same is expressly denied, are not "material" within the meaning of the Lanham Act and attendant case law interpreting said act, and are not likely to influence purchasing decisions by BAH's customers, and as such, cannot serve as the basis for BAHs' claims.

**TWENTY-THIRD DEFENSE**

To the extent that the Letter or Lilly's advertisements and published information constitute opinions held by Lilly or others, said opinions are not actionable under the Lanham Act, and may not serve as the basis for BAH's claims.

**TWENTY-FOURTH DEFENSE**

Any complained of statements by Lilly which meet the definition of "puffing" or "puffery" within the meaning of case law interpreting the Lanham Act are not actionable, and may not serve as the basis for BAH's claims.

**TWENTY-FIFTH DEFENSE**

BAH's claims are barred because BAH cannot demonstrate any likelihood that veterinarians will be confused or misled as to the substance of the claims made.

**TWENTY-SIXTH DEFENSE**

BAH's claims are barred because BAH failed to mitigate its damages, if any.

**RESERVATION OF RIGHTS**

Lilly reserves the right to supplement its answer and affirmative defenses with additional claims and defenses that become available or apparent during the course of investigation, preparation, or discovery and to amend its answer accordingly.

Upon completion of discovery, Lilly reserves the right to amend this Answer to assert additional claims or defenses as warranted by the applicable evidence.

**JURY DEMAND**

Lilly hereby demands a trial by jury.

WHEREFORE, Defendant Eli Lilly and Company demand that the Complaint in this action be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorney's fees incurred in the defense of this action, and that this Court grant Lilly any and all additional relief that is just and proper in these circumstances.

Dated: New York, New York  
May 25, 2011

Respectfully submitted,

/s/ Adam B. Michaels  
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